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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,850	11/19/2001	John F. Gordon	111465-128	7587

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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/988,850	GORDON ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *1-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 7, 19, and 20 is acknowledged and has been entered.

2. Claims 1-28 are pending.

3. Claims 1-6 have been withdrawn.

Rejections Withdrawn

4. Applicant's arguments, see pgs 9, filed October 26, 2004, with respect to the rejection of claim 19 under 35 U.S.C. 112, second paragraph, have been fully considered and are persuasive. The rejection of claim 19 under 35 U.S.C. 112, second paragraph, has been withdrawn.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 7-10, 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen [US 6,030,581] in view of Burd [US 5,518,930].

With respect to claims 7, 20, 23, Virtanen discloses an optical disk having a substantially self-contained assay means for localizing an analyte suspected of being in a sample to at least one, predetermined location. Specifically, Virtanen teaches an optical disk comprising a plurality of assay sectors, each comprising a substrate, a separation chamber (analyte separation sector) including a first inlet port, a filter means associated with said separation chamber, a mixing

chamber (sample preparation sector) in direct fluid communication with said separation chamber, and a first detection chamber (assay site) where the analyte binds to (column 5, lines 40-45) in fluid communication with the first mixing chamber (figs 1, 3). Virtanen fails to teach that the assay sectors share a common separation chamber for distributing fluid into multiple mixing chambers. Instead Virtanen teaches separate separation chambers, each having an inlet port.

Burd, however, teaches a central reservoir (separation chamber) that separates fluid such as plasma (column 5, lines 23-25) into a plurality of chambers (figs. 1A-1E, column 5, lines 58-67), such that simultaneous or parallel filling is possible (column 2, lines 35-41). Burd further teaches that simultaneous or parallel filling of the cuvettes is often desired, particularly when chemical analyses depend on reaction rate (column 1, lines 29-41). Burd also teaches that liquid measurement and separation steps should be simple and take place in relatively short times, with little or no intervention or manipulations by the operator (column 1, lines 45-56).

Therefore, it would have been obvious in the disk of Virtanen to have a central reservoir that separates fluid into a plurality of chambers, such that simultaneous or parallel filling is possible, particularly in chemical analyses that depend on reaction rate.

7. With respect to claims 8-9, 21, the mixing chambers of Virtanen contain a second inlet port, namly a reagent train provided to deliver as needed the necessary reagents in the proper order to the sample preparation segment (column 5, lines 31-35).

8. With respect to claims 10-13, 22, 24-26, Virtanen teaches that the bio-disc can be made from two halves, where the lower half may contain all the components (column 4, lines 62-67) and a upper half comprises a cover containing only a few components such as electrodes and wires. The components may be glued or melted together (column 5, lines 3-6).

9. With respect to claims 16-19, Virtanen teaches chambers can be located on an optical disc for assays, along with software on the disk associated with an assay for a particular analyte or analytes (column 4, lines 25-31). Virtanen further teaches that a reflective element can be used to monitor liquid flow during the assay (column 7, lines 9-20), such as reflective gold spheres or opaque latex spheres (column 8, lines 50-55).

10. Claims 14, 15, 27, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen [US 6,030,581] in view of Burd [US 5,518,930], as applied to claims 7, 20 above, and further in view of Chow [US 6,167,910].

With respect to claims 14-15, 27-28, Virtanen teaches the use of an upper half and lower half, as discussed above. Virtanen does not teach the use of a channel layer, with separation, mixing, and detection chambers formed in the channel layers.

Chow, however, does teach the use of multi-layered channels and chambers. Chow further teaches that providing multi-layered channel structures and networks and taking advantage of both surfaces of planar substrates, optimal use of substrate materials is permitted, allowing further miniaturization of fluidic processes and providing cost advantages in terms of substrate conservation (col.3, lines 10-26).

Therefore it would have been obvious in the device of Virtanen to have a channel layer, with separation, mixing, and detection chambers formed in the channel layer, as suggested by Chow, in order to allow further miniaturization of fluidic processes and providing cost advantages in terms of substrate conservation.

11. Claim 20-26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Coleman [US 3,799,742] in view of Virtanen [US 6,030,581].

With respect to claims 7, 20, 23, Coleman teaches an analyte test container comprising a separation chamber (reception chamber) with an inlet formed when a closure is pushed down to rupture membrane 302 and, a filter means in fluid connection with the separation chamber (fine mesh filter), multiple mixing chambers (reaction chambers) in direct fluid communication with the separation chamber and not in direct fluid communication with each other, and multiple detection chambers (cuvettes) (figs. 22, 29, 35, col. 14, lines 21-57, col.15, line 15-36, col.21, lines 15-49). Coleman, however, fails to teach that the container is configured to be capable of being rotated and transferring fluid from chamber to chamber in response to the rotation of the container, or the presence of capture zones.

Virtanen, however, does teach chambers can be located on an optical disc for assays, along with software on the disk associated with an assay for a particular analyte or analytes (column 4, lines 25-31). Virtanen teaches that such optical discs allow for assays to be performed quickly efficiently, accurately and at low cost, by combining diagnostic assays with computers and compact disk technology (column 1, lines 48-59). Virtanen further teaches that analytes bind to predetermined regions on the disk, allowing for identification of a particular analyte with the location at which it is bound (column 5, lines 45-52).

Therefore, it would have been obvious for the analyte test container to be adapted to an optical disc, as suggested by Virtanen, in order to allow for assays to be performed quickly efficiently, accurately and at low cost, and also to include capture zones, where analytes bind to

predetermined regions on the disk, in order to allow for identification of a particular analyte with the location at which it is bound.

12. With respect to claim 21, Coleman teaches the presence of inlet ports connected to the mixing chamber (fig. 22 (318, 322, and between 312 and 314, 316), fig. 29 (530, 560), fig. 35 (770, 772, 790, 800), col. 14, lines 21-57, col. 15, line 15-36, col.21, lines 15-49).

13. With respect to claim 22, Coleman teaches that the cover portion cooperates with the tray portion to provide closed chambers within the container body (col.5, lines 20-25). Joinder may be effective by a suitable adhesive or by cohesive bonding.

14. With respect to claim 23, Virtanen teaches that the analyte binds to predetermined sites on the disk (column 5, lines 40-45)

15. With respect to claims 24-26, Coleman teaches that the cover portion cooperates with the tray portion to provide closed chambers within the container body (col.5, lines 20-25). Joinder may be effective by a suitable adhesive or by cohesive bonding.

16. With respect to claims 8, 9, Coleman teaches the presence of inlet ports connected to the mixing chamber (fig. 22 (318, 322, and between 312 and 314, 316), fig. 29 (530, 560), fig. 35 (770, 772, 790, 800), col. 14, lines 21-57, col. 15, line 15-36, col.21, lines 15-49).

17. With respect to claims 10-13, Coleman teaches that the cover portion cooperates with the tray portion to provide closed chambers within the container body (col.5, lines 20-25). Joinder may be effective by a suitable adhesive or by cohesive bonding.

18. With respect to claims 16-19, Virtanen teaches chambers can be located on an optical disc for assays, along with software on the disk associated with an assay for a particular analyte or analytes (column 4, lines 25-31). Virtanen further teaches that a reflective element can be used

to monitor liquid flow during the assay (column 7, lines 9-20), such as reflective gold spheres or opaque latex spheres (column 8, lines 50-55).

19. Claims 14, 15, 27, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coleman [US 3,799,742], in view of Virtanen [US 6,030,581], as applied to claims 7, 20 above, and further in view of Chow [US 6,167,910].

With respect to claims 14-15, 27-28, Coleman teaches the use of a cap and substrate, as discussed above. Coleman does not teach the use of a channel layer, with separation, mixing, and detection chambers formed in the channel layers.

Chow, however, does teach the use of multi-layered channels and chambers. Chow further teaches that providing multi-layered channel structures and networks and taking advantage of both surfaces of planar substrates, optimal use of substrate materials is permitted, allowing further miniaturization of fluidic processes and providing cost advantages in terms of substrate conservation (col.3, lines 10-26).

Therefore it would have been obvious in the device of Coleman and Sheppard, Jr. et al to have a channel layer, with separation, mixing, and detection chambers formed in the channel layer, as suggested by Chow, in order to allow further miniaturization of fluidic processes and providing cost advantages in terms of substrate conservation.

Response to Arguments

20. Applicant's arguments with respect to claims 7-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

21. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
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02/05/05